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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/754,065	01/07/2004	Michael Principe	7419-01	6521

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COLGATE-PALMOLIVE COMPANY
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EXAMINER

ROBERTS, LEZAH

ART UNIT	PAPER NUMBER
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1614

MAIL DATE	DELIVERY MODE
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05/03/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/754,065

Applicant(s)

PRENCIPE ET AL.

Examiner

Lezah W. Roberts

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on 22 December 2006.

2a) ☐ This action is FINAL.

2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1-11, 13-21, 24 and 25 is/are pending in the application.

4a) Of the above claim(s) 1-11, 13 and 14 is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) 15-21 and 24-25 is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some * c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. _____.

3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 22 Dec 2006.

4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.

5) ☐ Notice of Informal Patent Application

6) ☐ Other: _____.

DETAILED ACTION

This Office Action is in response to the Request for Continued Examination filed December 22, 2006. All rejections have been withdrawn unless stated below.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims

Claim Rejections - 35 USC § 103 – Obviousness (New Rejections)

Claims 15-21 and 24-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lawlor (WO 02/34221) in view of Miranda et al. (US 5,656,286) in further view of Chen (US 2003/0129148).

Lawlor teaches oral compositions comprising different combinations of polyorganosiloxane gum, polyorganosiloxane resin and a nonvolatile polydimethylsiloxane fluid. In one embodiment the viscosity of the final concentration ranges from 1Pa.s to 1000 Pa.s, which encompasses the instant claims. The gum to resin ratio is 1:1 to 1:7 and the ratio of gum to fluid is 1:2 to 1:8 (page 7-8). Silicone pressure adhesives are mentioned as being useful in personal care products. The actives used in the compositions include peroxides and percarbonates, which are incorporated in the compositions ranging from 0.1% to 35% (page 17, paragraph 3 and page 18, paragraph 1), which encompasses claims 20-21. In regards to the enhancing agent, the resin or fluid can be considered an enhancing agent because when they are mixed with the gum they make a substantive composition on the oral cavity. In other

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words they remain on the oral surface after a certain period of time elapses (page 9, paragraph 3). This encompasses claim 19. The composition may also comprise flavoring agents and block polymers of ethylene oxide and propylene oxide, which can be used as an adhesive enhancing agent as recited in claim 25. These components are incorporated into the compositions at concentrations ranging from 0.001% to 10% (page 26, paragraph 1). The reference differs from the instant claims insofar as it does not teach the compositions come in a dental tray and the pressure sensitive silicone polymers mentioned in the reference are used in the compositions.

Miranda discloses systems for delivering drugs to parts of the body such as the teeth using a combination of a pressure sensitive polymer and a soluble polyvinylpyrrolidone. The pressure sensitive adhesive controls drug delivery (see Abstract). The compositions may be used for dental applications to deliver oral agents (col. 12, lines 49-50). A pressure-sensitive adhesive is a viscoelastic material, which adheres instantaneously to most substrates with the application of very slight pressure and remains permanently tacky (col. 6, lines 35-38). The pressure adhesive polymer comprises 14-94% and the PVP comprises 2 to 10% (col. 9, lines 51-59), encompassing claims 17-19. Suitable silicone pressure-sensitive adhesives include condensation products of polydiorganosiloxane with a resin. Examples of these adhesives are incorporated by reference from US 4,585,836 and disclose 40 to 70 parts silicone resin and 30 to 60 parts polydiorganosiloxane in the claims (col. 11, lines 20-48). The reference differs from the instant claims insofar as it does not disclose

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whitening agents as one of the drugs used for dental applications and does not disclose delivering the compositions in a tray.

Chen teaches whitening compositions comprising a peroxide compound and a water-soluble polymer that creates a thick gel with high viscosity (paragraph 0050). The compositions are applied to the teeth by a dental tray. The dental tray holds the bleach in contact with teeth and prevents the bleach from flowing away from the teeth to contact soft tissues. Use of a dental tray permits the bleach to remain in intimate contact with teeth for long periods of time without requiring the patient to sit in a dental chair with retracted cheeks. The dental tray also acts as a barrier against dilution of the bleach by saliva and the eventual swallowing of the bleaching material in a short period of time (paragraph 0014). The reference differs from the instant claims insofar as it does not teach the non-water soluble whitening formulation.

It would have been obvious to one of ordinary skill in the art to have used the pressure sensitive adhesives and PVP in the compositions of the primary reference motivated by the desire to use an adhesion system that adheres instantaneously to most substrates with the application of very slight pressure and remains permanently tacky, as disclosed by the secondary reference.

It would have been obvious to one of ordinary skill in the art to have used a tray to deliver the compositions of the combined primary and secondary references motivated by the desire to avoid contact of the bleaching agent with the soft tissue and also avoid the bleach being diluted by saliva and swallowed, as disclosed by the tertiary reference.

Claim Rejections - 35 USC § 103 – Obviousness (Previous Rejection)

1) Claims 23-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lawlor (WO 02/34221) in view of Chen (US 2003/0129148) as applied to claims 15-19 and 20-21 above, and further in view of Pfister et al. (US 5,232,702). The rejection is maintained in regards to claims 24-25 and applied to claims 15-21.

Applicant argues there is no disclosure in Lawlor or Chen to motivate one to select a hydrophobic polymer that is designed for transdermal drug delivery to be used in an application where the polymer is applied to the teeth. Pfister et al. does not disclose using a silicone pressure sensitive outside of transdermal delivery. Lawlor and Chen do not disclose selecting a condensation product of a silicon resin and an organosiloxane as the hydrophobic polymer. This argument is not persuasive.

Lawlor does mention silicone pressure sensitive adhesives and how work is being done to incorporate silicone polymers in personal care compositions. Pfister et al. discloses the advantage of using these polymers as oppose to the components separately, as disclosed in Lawlor. One of ordinary skill in the art would be motivated to use pressure sensitive adhesives found in the art that are used to deliver medicinal agents and/or other active agents. Pfister et al. discloses operable silicone adhesive that are beneficial for delivering active agents. Therefore it would be obvious to use the pressure sensitive polymers in the compositions of Lawlor because of the advantages disclosed by Pfister et al. and because they are suitable for delivering medicinal agents to the oral cavity.

2) Claims 23-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yue et al. (WO 01/01939) in view of Chen (US 2003/0129148) as applied to claims 15-19 and 20-21 above, and further in view of Pfister et al. (US 5,232,702). The rejection is maintained in regards to claims 24-25 and applied to claims 15-21.

Applicant argues there is no disclosure in Yue et al. or Chen to motivate one to select a hydrophobic polymer that is designed for transdermal drug delivery to be used in an application where the polymer is applied to the teeth. Pfister et al. does not disclose using a silicone pressure sensitive outside of transdermal delivery. Yue and Chen do not disclose selecting a condensation product of a silicon resin and an organosiloxane as the hydrophobic polymer. This argument is not persuasive.

Pfister et al. discloses the advantage of using these polymers as oppose to the components separately, as disclosed in Yue. One of ordinary skill in the art would be motivated to use pressure sensitive adhesive found in the art that are used to deliver medicinal agents and/or other active agents. Pfister et al. discloses operable silicone adhesive that are beneficial for delivering active agents. Therefore it would be obvious to use the pressure sensitive polymers in the compositions of Yue because of the advantages disclosed by Pfister et al. and because they are suitable for delivering medicinal agents to the oral cavity.

Claims 15-21 and 24-25 are rejected.

Claims 1-14 are withdrawn.

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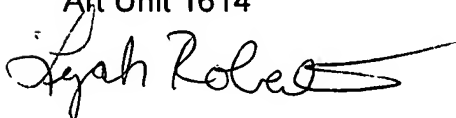
No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lezah W. Roberts whose telephone number is 571-272-1071. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Lezah Roberts
Patent Examiner
Art Unit 1614



Frederick Krass
Primary Examiner
Art Unit 1614

